NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE THALOMID AND REVLIMID ANTITRUST LITIGATION.

Civil No.: 14-6997 (KSH) (CLW)

Opinion

Katharine S. Hayden, U.S.D.J.

I. Introduction

International Union of Brick Layers and Allied Craft Workers Local 1 Health Fund ("IUB"), individually and on behalf of all others similarly situated, sued Celgene Corporation ("Celgene") for alleged violations of federal antitrust laws and state antitrust and consumer laws. (D.E. 1 (14-6997) ("IUB Compl.").) The City of Providence ("Providence") filed a complaint against Celgene that raised similar allegations and claims. (D.E. 1 (15-1605) ("Providence Compl.").) Both complaints were consolidated under docket number 14-6997. (D.E. 32 (14-6997); D.E. 5 (15-1605).)[1]

The motion practice in this case developed as follows. Celgene moved to dismiss IUB's complaint under Fed. R. Civ. P. 12(b)(6) on February 3, 2015, and IUB filed its opposition on March 17, 2015. (D.E. 20 (14-6997); D.E. 29 (14-6997).) Eight days later, on March 25, a stipulation and order was entered consolidating IUB's and Providence's lawsuits, and the parties agreed that Celgene's motion to dismiss IUB's complaint would apply to the common issues in Providence's complaint and that Celgene would file a second motion to dismiss that complaint's unique state law claims. (D.E. 32 (14-6997); D.E. 5 (15-1605).) Before filing the motion to

[1] The Court will refer to IUB and Providence collectively as plaintiffs.

dismiss Providence's complaint, Celgene filed a reply to IUB's opposition on March 30, 2015. (D.E. 31 (14-6997).) It then filed the motion to dismiss the unique state law claims in Providence's complaint on April 20, 2015 (D.E. 35 (14-6997)), and Providence filed its opposition on May 4, 2015, joining the arguments raised by IUB in its opposition that applied to their federal claims, while addressing Celgene's reasons for dismissal of its individual state law claims. (D.E. 40 (14-6997).) Celgene filed its reply brief to Providence's opposition on May 11, 2015. (D.E. 41 (14-6997).) Together, Celgene's motions seek dismissal of the entirety of plaintiffs' complaints.

Celgene, a branded manufacturer, identifies Thalomid and Revlimid as two of its most well-known products. Their generic names are thalidomide and lenalidomide. The former has a history – it was developed originally as a sleeping pill for pregnant women, was discovered to cause serious birth defect and other side effects, and was banned for decades. Because of this, when Celgene developed thalidomide as a treatment for a form of leprosy, the FDA required restricted distribution programs before granting approval to the distribution of Thalomid and Revlimid (the latter having been developed to treat different disorders but considered to pose similar threats). Celgene has amassed what it describes as a significant portfolio of unexpired patents which cover Thalomid and Revlimid as medicines and also their delivery without the risk of fetal exposure.

IUB, which maintains its principal place of business in Wallingford, Connecticut, purchased Thalomid and Revlimid for its members in Massachusetts and Nebraska, or partially reimbursed members who purchased the drugs. Providence, a municipal corporation, is a "self-insured health and welfare benefit plan" located in Providence, Rhode Island, that purchased and/or provided reimbursement for Thalomid and Revlimid on behalf of "its active and retired public employees and their dependents who reside in Florida, Kansas, Massachusetts, New Jersey,

North Carolina, and Pennsylvania." Central to plaintiffs' theory of their lawsuit as indirect purchasers of these drugs is Celgene's dominance over the market for thalidomide and lenalidomide, and how/if generic manufacturers will enter the market. As such, the Hatch-Waxman Act and the Food and Drug Administration ("FDA") regulations that govern the approval of pioneer and generic drugs are critical to this litigation.

Plaintiffs contend that Celgene fraudulently obtained patents covering its distribution methods, and that then Celgene manipulated the FDA regulatory scheme and Hatch-Waxman Act to prevent or delay generic manufacturers from obtaining FDA approval for generic versions of Thalomid and Revlimid by bringing sham infringement lawsuits. They contend further that Celgene withheld samples of thalidomide and lenalidomide from generic manufacturers (but not from researchers) to foil their efforts to gain FDA approval for generics. According to plaintiffs, Celgene's only purpose for the foregoing conduct was to maintain its monopoly over the market for thalidomide based drugs in order to continue to charge consumers supracompetitive prices. Plaintiffs' federal and state antitrust claims and unfair competition and unjust enrichment claims against Celgene are brought on behalf of indirect purchasers in several states, the District of Columbia, and Puerto Rico who paid or provided reimbursement for those drugs, other than for re-sale since November 7, 2010. (IUB Compl., ¶ 7; Providence Compl., ¶ 8.)

In deciding Celgene's motion to dismiss, the Court addresses the arguments raised in Celgene's moving briefs (D.E. 20-1 ("Celgene Br."); D.E. 35-1); IUB's and Providence's opposition briefs (D.E 29; D.E 40); and Celgene's replies to plaintiffs' respective opposition briefs. (D.E. 31; D.E. 41.)

II. Background

The facts taken from the plaintiffs' complaints are assumed as true, and are construed in favor of plaintiffs for purposes of Celgene's motions. *Phillips v. Cnty. of Allegheny*, 51 F.3d 224, 231 (3d Cir. 2008).

A. Overview of FDA Regulations

1. Development of Pioneer and Generic Drugs

The parties largely agree about what statutory and regulatory law applies, and how it works. Pharmaceutical manufacturers seeking to market a pioneer drug must obtain the Food and Drug Administration's ("FDA") approval by filing a New Drug Application ("NDA"). 21 U.S.C. § 355(a). The NDA must include information pertaining to the proposed drug's safety and effectiveness, along with the patents that cover it. § 355(b)(1). For each patent, the NDA must list:

> the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id.; *see also* 21 C.F.R. § 314.53(b). The manufacturer is required to list these patents in the "Approved Drug Products and Therapeutic Equivalence Evaluations," known as the Orange Book, which is published by the FDA. The manufacturer must also list any patent it obtains subsequently that covers the drug, and do so within 30 days after the patent is issued. 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(c)(2)(ii). The plaintiffs assert that because the FDA's limited resources prevent it from verifying the patent information, the agency relies on the representations submitted by the manufacturers. (IUB Compl., ¶ 24; Providence Compl., ¶ 23.)

The development and approval of generic drugs was the focus of the Hatch-Waxman Act, 21 U.S.C. § 355, which aims to "(1) induc[e] pioneering research and development of new drugs and (2) enabl[e] competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). Instead of an NDA, a manufacturer seeking approval of a generic version of a pioneer drug may file an Abbreviated New Drug Application ("ANDA") demonstrating that its generic version is the "bioequivalent" of the approved, pioneer drug. 21 U.S.C. § 355(j). The ANDA applicant is not required to conduct its own tests to prove a drug's efficacy and safety and may rely on the pioneer manufacturer's research and data. § 355(j)(2)(A)(iv). The ANDA needs to establish that the generic drug contains the same active ingredient or ingredients, dosage form, route of administration, and strength as the pioneer drug, and that the generic drug is absorbed to the same extent and at the same rate. § 355(j)(2), (j)(8)(B).

The ANDA applicant must submit a certification for each patent covering the pioneer drug listed in the Orange Book that makes one of the following representations: (1) that no patent information was filed with the FDA covering the pioneer drug; (2) that the listed patent expired; (3) that the patent will expire on a certain date and that the ANDA's approval should be delayed until then; or (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." § 355(j)(2)(B)(vii). The fourth representation is often referred to as a Paragraph IV Certification. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008).

The ANDA applicant must notify the patent holder (frequently the pioneer manufacturer) when filing a Paragraph IV Certification. 21 U.S.C. § 355(j)(2)(B). Two contingencies affect an ANDA for which a Paragraph IV Certification is filed:

> (1) whether the pioneer drug company brings an infringement action within 45 days of learning of the Paragraph IV ANDA filing, and (2) whether the company seeking approval was the first one to file an ANDA containing a Paragraph IV certification to the listed patent.

Janssen, 540 F.3d at 1356. If the brand name manufacturer does not sue within 45 days, the FDA may grant final approval to the ANDA after all other requirements are satisfied. 21 U.S.C. § 355(j)(5)(B)(iii). But if an infringement action is instituted within that 45-day period, approval is stayed for 30 months or until resolution of the lawsuit. *Id.* In this regard, the mere act of filing a Paragraph IV Certification constitutes patent infringement allowing the patent holder to immediately file suit against the ANDA applicant. 21 U.S.C. § 271(e)(2)(A).

The Hatch-Waxman Act provides a 180 day period of exclusivity to the first generic manufacturer to file a Paragraph IV Certification once its generic drug is approved. *Janssen*, 540 F.3d at 1356; *see also* 21 U.S.C. § 355(j)(5)(B)(iv). That 180-day period begins to run from the date the generic drug is first marketed. § 355(j)(5)(B)(iv)(I). An ANDA applicant that fails to market the drug upon the expiration of certain time frames forfeits that exclusivity period. § 355(j)(5)(D)(i)(I).

2. <u>FDA Citizen Petitions</u>

A private entity may file a citizen petition requesting, among other things, that the FDA issue, amend, or revoke a regulation, or that the agency take or refrain from any administrative action. 21 C.F.R. § 10.30(b). The citizen petition must contain "the factual and legal grounds on which the petitioner relies." *Id.* Citizen petitions are sometimes filed in response to an ANDA, but the FDA cannot delay the application's approval unless it determines "that delay is necessary to protect the public health." 21 U.S.C. § 355(q)(A)(ii).

B. Celgene's Development of Thalomid and Revlimid

After the worldwide ban of thalidomide was lifted in 1998, Celgene obtained FDA approval to market and distribute it under the brand name Thalomid to treat erythema nodosum leprosum, a form of leprosy. (IUB Compl., ¶ 66-67.) In 2005, Celgene received approval to manufacture and market Revlimid, or lenalidomide, a "thalomid analogue." (*Id.* ¶69; Providence Compl., ¶ 109.)

The FDA conditioned its approval on Celgene's developing restricted distribution programs for the two drugs. (Providence Compl. ¶ 4.) In 1998, Celgene devised and implemented a program known as S.T.E.P.S., the acronym for the System for Thalidomide Education and Prescribing Safety. (IUB Compl., ¶ 67.) In 2010, S.T.E.P.S. was replaced by REMS, Risk Evaluation and Mitigation Strategies. (Providence Compl., ¶ 4.) All thalidomide and lenalidomide distributors, pharmacists, and recipient patients are required to enroll in the REMS program as a condition of obtaining Thalomid or Revlimid. (*Id.* ¶ 4.)

Celgene acquired six patents covering the procedures for the approved distribution of Thalomid and Revlimid: Patent No. 6,045,501 ("the '501 Patent"); Patent No. 6,315,720 ("the '720 Patent"); Patent No. 6,561,976 ("the '976 Patent"); Patent No. 6,561,977 ("the '977 Patent"); Patent No. 6,755,784 ("the '784 Patent"); and Patent No. 8,513,886 ("the '886 Patent") (collectively "the Distribution Patents"). (Providence Compl., ¶ 108.) In 1998, when the FDA approved Thalomid, Celgene had listed only the '501 Patent in the Orange Book. (*Id.* ¶ 110.) Celgene added the other patents under Thalomid as they were obtained: the '720 Patent in 2001; the '976 Patent and '977 Patent in 2003; and the '784 Patent in 2004. (*Id.* ¶¶ 108, 110.) Celgene listed the same patents under Revlimid when the FDA approved it in 2005. (*Id.* ¶ 110.) In 2012, Celgene added the '886 Patent to the Orange Book listings for both Thalomid and Revlimid. (*Id.*

¶¶ 108, 110.) The Distribution Patents, according to plaintiffs, generally claim "the use of registries to register patients, prescribers, and pharmacies when the patient is using a particular drug that should not be exposed to a fetus or contraindicated individual"; periodic testing of patients for risks related to the drug; patient counseling about those risks; limitations on the amount of drug dispensed; and/or prescribing or dispensing the drug to patients after determining the risks are acceptable. (*Id.* ¶ 110; IUB Compl., ¶ 123.)

C. <u>Celgene's Monopoly Power in the Relevant Markets and its Anti-Competitive Conduct.</u>

Plaintiffs assert that Celgene had monopoly power over the markets for the drugs in question, and gained and maintained its monopoly power by anti-competitive conduct that successfully suppressed the entry of generic thalidomide and lenalidomide products into the market. According to plaintiffs, Celgene "possessed and exercised monopoly power over the markets for Thalomid and Revlimid, because it had the power to raise and/or maintain the price of Thalomid and Revlimid at supracompetitive levels without losing substantial sales." (Providence Compl., ¶ 269.) Plaintiffs recite a "dramatic increase" in the revenue Celgene derives from sales of the drugs, which have amounted to $20.9 billion in revenue since 2006. (IUB Compl., ¶ 3.) In the first quarter of 2014 alone, Celgene recorded $3.6 billion in revenue from Revlimid sales and $164 million from Thalomid sales. (Providence Compl., ¶ 5; IUB Compl., ¶ 3.) When it was first approved, Thalomid cost approximately $6 per capsule and now it costs between $212 and $357. (IUB Compl., ¶ 3.) Celgene charges $500 per capsule of Revlimid. (*Id.*)

Celgene's "overarching anti-competitive scheme" consisted of using its REMS programs as a pretext to deny generic manufacturers access to samples of Thalomid and Revlimid necessary to complete bioequivalency testing; fraudulently obtaining various patents, including the distribution method patents; engaging in sham litigation and, in certain cases, entering into

confidential settlements that may have included an anti-competitive reverse payment; and filing baseless citizen petitions with the FDA. (Providence Compl. ¶ 260.) This conduct was undertaken to prevent and delay the sale of generic thalidomide and lenalidomide products "by suppressing the ability of generic manufacturers to compete through the most efficient means of competition available under the applicable statutory and regulatory construct, including the Hatch-Waxman Act." (*Id.*)

1. <u>Celgene Restricts the Supply of Thalidomide and Lenalidomide</u>

Plaintiffs assert that Celgene actively sought to prevent generic drug manufacturers from obtaining samples of thalidomide and lenalidomide containing the active pharmaceutical ingredient ("API") essential for bioequivalency studies and validation testing that ANDAs require. (IUB Compl., ¶¶ 70, 80; Providence Compl., ¶ 61.) They contend that Celgene used the S.T.E.P.S. and REMS programs as a pretext to deny generic manufacturers access to the samples and that it also attempted to limit the availability of samples from other potential thalidomide API suppliers.

According to the allegations, two drug manufacturers, Mylan Pharmaceuticals and Lannett Company, sought to develop and market generic versions of Thalomid, and Dr. Reddy's Laboratory wanted to develop a generic alternative to Revlimid. (*Id.* ¶¶ 88, 99, 118; Providence Comp., ¶¶ 73, 81.) The three companies asked Celgene for samples to use in their bioequivalency studies. (IUB Compl., ¶¶ 93, 99, 118.) Plaintiffs claim that Celgene refused, claiming that providing samples would violate its S.T.E.P.S. distribution program. (*Id.* ¶¶ 93, 110, 119-121.) This was contrary to FDA communications with the generic manufacturers, which they forwarded to Celgene, and which stated that the agency would not take action if Celgene provided the samples. (*Id.* ¶¶ 90, 93, 105, 110.)

Faced with Celgene's refusal, Lannett sought an injunction, and plaintiffs allege that Celgene settled in 2011 on confidential terms. (*Id.* ¶ 95-96.) Mylan sued Celgene in this district in April 2014 after it refused to provide Revlimid samples. (*Id.* ¶ 112.) Celgene unsuccessfully moved to dismiss. (Providence Compl., ¶ 99.) Dr. Reddy's filed a citizen petition with the FDA in June 2009, asserting that Celgene improperly denied it access to Revlimid samples for bioequivalency testing. (IUB Compl., ¶ 120.) The complaints do not indicate how that effort fared.

According to IUB's complaint, Barr Laboratories ("Barr") successfully obtained the thalidomide API in 2004 from Seratec S.A.R.L. ("Seratec"), a French company. (*Id.* ¶¶ 81, 82.) After Barr completed its bioequivalency testing, it needed a Drug Master File ("DMF") reference letter from Seratec to include with its ANDA submissions. (*Id.* ¶ 82.) Seratec refused Barr's request. (*Id.* ¶ 83.) Plaintiffs claim there was an "exclusive thalidomide supply arrangement" between Celgene and Seratec that Celgene had demanded so as "to interfere with potential generic competitors' ability to market a generic version of Thalomid." (*Id.*) Barr had to find an alternative supplier and repeat its bioequivalency testing, which delayed its ANDA filing until December 2006. (*Id.* ¶ 84; Providence Compl., ¶ 72.) Plaintiffs assert that Barr's application would have been submitted "years earlier," and a lower-priced generic version of Thalomid would have been available for purchase, had Celgene not interfered. (*Id.* ¶ 85; Providence Compl., ¶ 72.)

According to plaintiffs, despite its practice of denying generic manufacturers access to samples, Celgene has supplied samples to several research institutions when requested without raising S.T.E.P.S. or the REMS programs as a bar. (*Id.* ¶¶ 76, 77.)

2. Celgene's Fraudulently Obtained Patents

Plaintiffs allege that Celgene fraudulently obtained the Distribution Patents covering S.T.E.P.S. and REMS in order to extend its monopoly power over the thalidomide and lenalidomide markets, and engaged in sham enforcement litigation. (Providence Compl., ¶¶ 107, 175.) They claim that when it applied for its Distribution Patents, Celgene withheld "information known to be material to patentability with the intent to deceive" the United States Patent and Trademark Office ("USPTO") regarding prior art that it knew about. (IUB Compl., ¶¶ 129-33.) And plaintiffs take the position that Celgene listed the Distribution Patents in the Orange Book solely to discourage thalidomide and lenalidomide ANDA filings. (*Id.* ¶ 127.)

The prior art consists of ten "[p]rocedures for safe distribution and use of dangerous drugs," which may be grouped into three categories: pharmaceutical distribution programs and packaging, publications, and meetings. From the allegations, it appears that all relate to the methods that were instituted in connection with distributing Clozaril, Clozapine, and Accutane safely, and how this might apply to thalidomide.

Pharmaceutical Distribution Programs and Packaging

1. Clozaril Patient Monitoring Service ("CPMS");

2. Accutane Pregnancy Prevention Program ("PPP");

3. Accutane PPP Package ("PPP Package"), a patient and prescriber information packet for Accutane released in 1994.

Publications

4. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services* 47(1): 52-56 (1996) ("Honigfeld I");

5. Honigfeld, *et al.*, "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National

Registry," *J. Clin. Psychiatry* 59 suppl. 3: 3-7 (1998) ("Honigfeld II");

6. "Guide to the Clozaril Patient Monitoring Service," ("the Guide"), which was published in 1997, and described the details of CPMS;

7. Zeldis, *et al.*, "Steps: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("the Zeldis Article").

<u>Meetings</u>

8. CDC Meeting - a Centers for Disease Control ("CDC") public meeting titled "Preventing Birth Defects Due to Thalidomide Exposure" and its corresponding transcript from March 26, 1997 ("CDC Transcript");

9. CDER Meeting - a public meeting held by the Center for Drug Evaluation and Research of the FDA on September 4 and 5, 1997;

10. NIH Meeting - a public workshop held on September 9 and 10, 1997, by the National Institutes of Health ("NIH"), FDA, and CDC entitled "Thalidomide: Potential Benefits and Risks Open Scientific Workshop."

(*Id.* ¶ 131.)

Plaintiffs contend that Bruce Williams, a Celgene employee and the named inventor of the Distribution Patents, and Dr. Jerome Zeldis, then-president of medical affairs at Celgene, attended the CDC Meeting in March 1997 at which CPMS and PPP were discussed as foundations for developing similar distribution methods and controls for thalidomide. (*Id.* ¶¶ 160, 161.) And they go on to assert that later that same year, Williams gave presentations at both the CDER meeting and NIH meeting regarding the creation of a distribution and control program for thalidomide that was a corollary to CPMS and PPP. (*Id.* ¶¶174, 175, 179, 180).) Plaintiffs also assert that Williams, along with other Celgene employees, authored and published the Zeldis Article in 1999, which describes S.T.E.P.S. and acknowledges that the program was based on CPMS and PPP. (*Id.* ¶¶

165-67.) According to plaintiffs, the Zeldis Article cites to Honigfeld I and II in its discussion of CPMS. (*Id.* ¶ 168.)

Plaintiffs allege that nine of the ten examples they cite are prior art to all of the Distribution Patents. The exception is the Zeldis Article, which they assert is prior art to all except the ’501 Patent and ’976 Patent. (IUB Compl., ¶¶ 140, 143, 146, 149, 153, 156, 162, 164, 176, 181, 183.) They contend that Celgene omitted all prior art material to the ’501, ’720, ’976, ’977, and ’784 Patents’ applications. (*Id.* ¶¶ 184-191.) As to the ’886 Patent, plaintiffs maintain that Celgene disclosed eight references of prior art and only omitted the PPP Package and CDC transcript from its application. (*Id.* ¶ 197.). Plaintiffs charge that Celgene willfully and fraudulently withheld the prior art from the USPTO (IUB Compl., ¶¶ 190, 191, 208, 209), and as a consequence the Distribution Patents are invalid and unenforceable. Over all, plaintiffs allege that Celgene’s sole purpose in listing these patents in the Orange Book was to invoke the benefits of the 30-month stay in 21 U.S.C. § 355(j)(5)(B)(iii) should an ANDA be filed. (*Id.* ¶¶ 192, 194, 204.)

3. <u>Sham Litigation and Citizen Petition</u>

Plaintiffs further contend that Celgene engaged in “sham litigation” to enforce the Distribution Patents (IUB Comp., ¶¶ 211, 213, 226-29, 238; Providence Compl., ¶¶ 195, 210), and that Celgene filed a sham citizen petition in 2007 in response to Barr’s 2006 ANDA, urging the FDA to withhold approval. (IUB Compl., ¶¶ 212, 216, 220-22.) Factually, plaintiffs point to Celgene’s 2007 lawsuit against Barr after it filed its Paragraph IV Certification, which triggered the 30-month stay of FDA approval for Barr’s thalidomide ANDA. (*Id.* ¶¶ 213-15.) On May 26, 2010, not long after the stay expired, Celgene and Barr[2] reached a confidential settlement. (*Id.* ¶

[2] Plaintiffs appear to indicate that following the settlement agreement Barr was purchased by Teva, but because the allegations are unclear in this regard, the Court will continue to refer to this entity as Barr.

126.) These events "had the anti-competitive effect of keeping generic alternatives to Thalomid off the market." (*Id.*)

Plaintiffs allege that the settlements with Barr and Lannett are "reverse payment patent settlements," also known as pay-for-delay agreements.[3] (*Id.* ¶¶ 217, 239.) They maintain that Celgene paid the manufacturers either to delay or to postpone their entrance into the thalidomide or lenalidomide markets. (*Id.* ¶ 217, 218, 242; Providence Compl, ¶ 240.)

Celgene filed a patent infringement suit against Natco, whose Paragraph IV Certification was directed against the earliest five Distribution Patents, along with Patent No. 5,635,517 ("the '517 Patent"), Patent No. 6,281,230 ("the '230 Patent"), Patent No. 6,555,554 ("the '554 Patent"), Patent No. 7,119,106 ("the '106 Patent"), and the Patent No. 7,465,800 ("the '800 Patent"), which, according to plaintiffs, covered Revlimid's chemical composition. (*Id.* ¶¶ 225, 226.) While the lawsuit was pending, Celgene listed two more patents in the Orange Book covering Revlimid. (*Id.* ¶¶ 229, 230.) Natco filed a second Paragraph IV Certification on March 14, 2013, claiming those patents were also invalid, unenforceable, or not infringed by Natco's generic lenalidomide. (*Id.* ¶ 231.) Almost three years after it instituted the patent infringement suit against Natco, Celgene listed two other patents in the Orange Book under Revlimid: Patent No. 8,404,717 ("the '717 Patent") and Patent No. 8,431,509 ("the '598 Patent"). (*Id.* ¶ 232-33.) Through a series of amended complaints in its lawsuit against Natco, Celgene has, according to plaintiffs, pursued its goal of delaying generic entry into the Revlimid market. (*Id.* ¶ 238.)

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[3] In a reverse payment settlement, "Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars." *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

D. <u>Celgene's Overall Anti-Competitive Scheme</u>

Plaintiffs allege that Celgene engaged in an anti-competitive scheme to "block[] and delay[] generic Thalomid and Revlimid competition, disrupt[] the normal channels, and the statutory and regulatory mechanisms, by which generic competition takes place . . . , and exclude[] would-be generic competitors from the most efficient means of distributing their products." (*Id.* ¶ 243.) Were it not for Celgene's anti-competitive conduct, plaintiffs claim that generic versions of Thalomid and Revlimid would have entered the market, thus "driving down the cost" of thalidomide and lenalidomide products and increasing consumer choice. (Providence Compl., ¶¶ 243, 244.) They assert that "[t]he enormous cost savings" that generic drugs would afford consumers "outweigh" any justification that Celgene could offer and that any reasons it does put forth are pretextual. (IUB Compl., ¶ 248.) Plaintiffs conclude that Celgene did not maintain its monopoly power through "meritorious competition" but did so through unlawful, willful exclusionary conduct violating federal and state laws. (Providence Compl., ¶ 247.)

E. <u>Procedural History</u>

IUB filed its five-count class action complaint against Celgene on November 7, 2014, on behalf of:

> All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide or lenalidomide in any form, in the United States, and its territories for consumption by themselves, their families, or their members employees, insureds, participants, or beneficiaries at any time during the period of November 7, 2010 through and until the anticompetitive effects of [Celgene's] unlawful conduct cease.

(IUB Compl., ¶ 252.) Providence filed its five-count class action complaint on March 3, 2015, on behalf of a similarly defined class. (Providence Compl., ¶ 250.) IUB and Providence, in counts 1 and 2 of their complaints, allege that Celgene's scheme constituted unlawful monopolization and attempted monopolization under state law. (IUB Compl., ¶¶ 282-99; Providence Compl., ¶¶ 279-

92.) IUB asserts that Celgene violated 27 state laws in count 1 and 30 in count 2 (IUB Compl., ¶¶ 289, 295), and Providence relies on 25 state laws in count 1[4] and count 2.[5] (Providence Compl., ¶¶ 286, 292.) Count 3 of both complaints contends that Celgene engaged in unfair and deceptive trade practices under state law.[6] (IUB Compl., ¶¶ 296-99; Providence Compl., ¶¶ 293-96.) Plaintiffs, in their respective fourth counts, request injunctive relief under the Clayton Act, 15 U.S.C. § 26, ordering Celgene to cease its alleged anti-competitive activities, asserting that they contravene Section 2 of the Sherman Antitrust Act ("the Sherman Act"), 15 U.S.C. § 2.[7] (IUB Compl., ¶¶ 300-02; Providence Compl., ¶¶ 297-99.) The last claim contends that Celgene was unjustly enriched by its anti-competitive and unlawful acts in the form of the economic benefit conferred on it by plaintiffs and their prospective class when they purchased and/or provided reimbursement for the cost of Thalomid and/or Revlimid.[8] (IUB Compl., ¶¶ 303-15; Providence Compl., ¶¶ 300-12.)

[4] In count 1, both IUB and Providence allege Celgene's conduct violated the laws of Arizona, California, the District of Columbia, Florida, Illinois, Iowa, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Puerto Rico, South Dakota, Utah, Vermont, West Virginia, and Wisconsin. (IUB Compl., ¶ 289; Providence Compl., ¶ 286.) IUB also relies on the antitrust laws of Hawaii, Massachusetts, Missouri, and Tennessee. (IUB Compl., ¶ 289.) Providence claims that Celgene's acts also violated the antitrust laws of Kansas and Rhode Island. (Providence Compl., ¶ 286.)

[5] As for count 2, both IUB and Providence rely on the same states' antitrust laws that they relied on in count 1, and IUB adds New York's statute. (IUB Compl., ¶ 289; Providence Compl., ¶ 292.)

[6] IUB and Providence both rely on the laws of Arizona, Arkansas, California, the District of Columbia, Florida, Kansas, Idaho, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, and Virginia in count 3. (IUB Compl., ¶ 299; Providence Compl., ¶ 296.) IUB additionally brings claims in count 3 pursuant to Illinois, Maine, Massachusetts, Tennessee, and West Virginia statutes. (IUB Compl., ¶ 299.)

[7] Plaintiffs limit their request to injunctive relief for Celgene's alleged violations of the Sherman Act recognizing the Supreme Court's ruling in *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 747 (1977) that indirect purchasers may not obtain monetary relief for federal antitrust violations.

[8] The plaintiffs bring their unjust enrichment claims "under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana." (IUB Compl., ¶ 311; Providence Compl., ¶ 308.)

III. Discussion

A. Standard of Review

"Detailed factual allegations" are not required for a plaintiff to survive a motion to dismiss, but there must be more in the complaint than "the-defendant-unlawfully-harmed-me accusation[s]" and legal conclusions. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The plaintiff must set forth "'sufficient factual matter' to show that a claim is facially plausible" so as to permit "'the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678).

B. Sherman Act Claims – Plaintiffs' Fourth Counts

Celgene first challenges the fourth counts in plaintiffs' complaints, which bring claims under Section 2 of the Sherman Act and seek injunctive relief pursuant Section 16 of the Clayton Act. Section 2 of the Sherman Act makes it unlawful for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2. Injunctive relief is available to prevent "against threatened loss or damage by a violation of the antitrust laws" pursuant to the Clayton Act. § 26. To state a plausible claim for relief under Section 2 of the Sherman Act, the plaintiff must show that the defendant (1) possessed "monopoly power in the relevant market" and (2) willfully acquired or maintained that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563 570-71 (1966)) (internal quotation marks omitted).

1. **Antitrust Causation and Injury**

Celgene contends that plaintiffs lack antitrust standing, having failed to show antitrust causation or injury. The requirements of antitrust injury and standing, although mutually exclusive, often overlap. *See Animal Sci. Prods., Inc. v. Chin Minmetals Corp.*, 34 F. Supp. 3d 465, 492 (D.N.J. 2014) (McNulty, J.). To satisfy the requirements of injury, a plaintiff must show "(1) 'injury of the type the antitrust laws were intended to prevent,' and (2) injury that 'flows from that which makes the defendants' acts unlawful.'" *Int'l Raw Materials, Ltd. v. Stauffer Chem. Co.*, 978 F.3d 1318, 1328 (3d Cir. 1992) (quoting *Brunswick Corp. v. Pueblo Bowl-O Mat, Inc.*, 429 U.S. 477, 489 (1977)). And while an injury may be "causally related to an antitrust violation," it will not constitute antitrust injury "unless it is attributable to an anti-competitive aspect of the practice under scrutiny." *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990). Celgene's argument rests on two premises. First, it maintains that plaintiffs fail to plead causation and injury because the *Noerr Pennington* Doctrine immunizes it from antitrust liability for asserting its patents covering Thalomid and Revlimid against generic drug manufacturers.[9] Second, Celgene argues that its numerous patents covering Thalomid and Revlimid ("the Non-Distribution Patents") operate as an independent bar to market entry for generic versions of those drugs. Celgene therefore concludes that "[n]o generic manufacturer could have brought generic versions of Revlimid and Thalomid to market in any event, for the wholly independent reason that, as a matter of law Celgene can assert (and has asserted) patents in its portfolio that [plaintiffs do] not, and could not legitimately, challenge as having been fraudulently procured or sham asserted." (Celgene Br. at 2-3.)

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[9] The *Noerr Pennington* Doctrine derives its name from the Supreme Court's decisions in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965), on which it is based.

a. The *Noerr Pennington* Doctrine

Celgene contends that its conduct in asserting its patents is immune from antitrust liability under the *Noerr Pennington* Doctrine. Plaintiffs counter by asserting that Celgene engaged in sham litigation and obtained the Distribution Patents by committing fraud on the USPTO, stripping it of any immunity it could claim under *Noerr Pennington*.

"Whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws" is resolved applying Federal Circuit law, while Third Circuit law applies "to issues involving other elements of antitrust law." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). The *Noerr Pennington* Doctrine stands for the proposition that "the Sherman Act does not prohibit . . . persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly." *Noerr*, 365 U.S. at 136; *accord Pennington*, 381 U.S. at 670. This includes the use of "state and federal agencies to advocate their causes and points of view respecting resolution of their business and economic interests vis-à-vis their competitors." *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511 (1972). The Doctrine's goal seeks to avoid invasions on "the First Amendment right to petition," *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) (hereinafter "*PRE*"), even it is for "an improper purpose or motive," such as to destroy competition. *A.D. Bedell Wholesale Co, Inc. v. Philip Morris Inc.*, 263 F.3d 239, 250 (3d Cir. 2001).

The Supreme Court has carved out two exceptions to *Noerr Pennington* immunity. The first, which relates solely to patents, is based on *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). A plaintiff raising a *Walker Process* claim alleges that the defendant is "bringing a suit to enforce a patent with knowledge that the patent is

invalid or not infringed, and the litigation is conducted for anti-competitive purposes." *C.R. Bard, Inc. v. MS Sys., Inc.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998). *Noerr Pennington* immunity does not attach, and a defendant is liable under antitrust laws, when it procures a patent "by knowing and willful fraud" and "enforced the patent with knowledge of the fraudulent manner in which it was obtained." *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 506 (Fed. Cir. 2012); *see also Walker Process*, 382 U.S. at 179 (Harlan, J., concurring). The additional elements of a Section 2 claim, such as monopoly power, must also be shown. *See Hydril Co. LP v. Grant Prideco LP*, 474 F.3d 1344, 1349 (Fed. Cir. 2007) (stating that the other elements of a claim under Section 2 of the Sherman Act must be present when an antitrust violation is premised on a fraudulently obtained patent).

The second exception applies to "petitions and lawsuits that are a 'mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.'" *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999) (quoting *Noerr*, 365 U.S. at 144). In identifying sham litigation, a court must first assess whether the lawsuit is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. If so, the inquiry then turns to "whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental *process* -- as opposed to the *outcome* of that process -- as an anticompetitive weapon." *Id.* at 60-61 (citations and internal quotation marks omitted).

A patent owner can be stripped of antitrust immunity under either exception. The sham litigation exception precludes a patent holder from *Noerr Pennington* immunity if the suit is "based on a theory of infringement or validity that is objectively baseless," in that no reasonable person would believe that the patent was infringed or valid, and if it is "subjectively brought in bad faith."

Nobelpharma, 141 F.3d at 1072. "[I]f a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial," and the sham litigation exception does not apply. *Id*. For a *Walker Process* claim, in contrast, the mindset of the patent holder in enforcing a patent is irrelevant because, once it is shown that a patent was knowingly and willfully procured by fraud, the patent owner may not hide under shelter of *Noerr Pennington* irrespective of its reasons for bringing suit. *See Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007) ("A party who asserts such a fraudulently obtained patent may be subject to an antitrust claim.").

i. *Walker Process* Claim

Celgene argues that plaintiffs' allegations fall short of the heightened pleading standard of Fed. R. Civ. P. 9(b), which applies to *Walker Process* claims. "Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [US]PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). A plaintiff alleging that a patent was procured through fraud under *Walker Process* must show:

> (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted.

C.R. Bard, 157 F.3d at 1364. But "[a] mere failure to cite a reference to the [USPTO] will not suffice" as a willful omission because "the applicant could have a good-faith belief that disclosure was not necessary, or simply have forgotten to make the disclosure." *Dippin' Dots*, 476 F.3d at 1347 (citation and internal quotation marks omitted). "There must be evidence of intent separable from the simple fact of the omission." *Id.*

A patent applicant has a duty of candor to the USPTO, which includes disclosing all prior art, 37 C.F.R. § 1.56(a), and "[a] patent is invalid for anticipation if a single prior art reference

discloses each and every limitation of the claimed invention." *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Among the classes of prior art, the one relevant to the present matter is that which precludes the issuing of a patent when "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102(a)(1).

Plaintiffs allege that Celgene fraudulently procured the six Distribution Patents, the earliest of which was obtained on April 4, 2000, by knowingly omitting ten references of anticipatory prior art material to their patentability. (IUB Compl., ¶ 135.) Celgene argues these allegations fail to meet the heightened pleading standard of Fed. R. Civ. P. 9(b) because they do not explain how the prior art "materially differ[s] from, and/or was not cumulative of, the prior art" it disclosed to the USPTO while prosecuting the Distribution Patents. Celgene also contends that the pleadings are insufficient to show fraud on the USPTO because plaintiffs failed to explain how the references of prior art "are materially similar to, and/or anticipatory of," any of the Distribution Patents' claims.

According to plaintiffs, Celgene employees attended the CDER Meeting and NIH Meeting, easily raising the inference that Celgene was aware of those two references of prior art at all times before procuring the earliest Distribution Patent. (IUB Compl., ¶¶ 171, 172, 179, 180.) And plaintiffs assert that Williams, a named inventor of the Distribution Patents, gave presentations at both meetings about developing a restricted distribution program for thalidomide, extrapolating the methods used for Accutane and Clozaril. (*Id.* ¶¶ 174, 175, 179, 180.) Williams's knowledge of the Accutane and Clozaril programs raises the inference that he, and in turn Celgene, was aware of CPMS, PPP, and the PPP Package. This knowledge is further shown by the assertions that Williams and Zeldis were at the CDC Meeting during which PPP and CPMS were discussed. (*Id.* ¶¶ 159-61.) Plaintiffs also claim that the Zeldis Article, which Williams and other Celgene

employees authored, cites to Honigfeld I and II, implying a knowledge of those two references of alleged prior art. (*Id.* ¶¶ 165-168.) Last, Celgene included the Guide as prior art in the ’886 Patent’s application. (*Id.* ¶ 197.)

Plaintiffs note that Celgene included eight of the ten references of prior art in the 2010 application for the ’886 Patent, the latest of the Distribution Patents. (IUB Compl, ¶¶ 197-98.) This raises the inference that Celgene believed those eight references of prior art were material to the ’886 Patent’s application and the others as well. Plaintiffs therefore plausibly allege that Celgene willfully omitted the prior art from the prior applications with the intent to deceive the USPTO. The issuance of the patents demonstrates justifiable reliance by the USPTO. *See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1361 (Fed. Cir. 2004) (finding that the USPTO justifiably relied on a patent application’s omission because it issued the patent), *rev’d on other grounds*, 546 U.S. 394 (2006). Plaintiffs’ allegations, taken as true, sufficiently allege, under the heightened pleading standard of Fed. R. Civ. P. 9(b), that Celgene obtained the Distribution Patents by committing fraud on the USPTO.[10]

Plaintiffs assert that Celgene sought to enforce the Distribution Patents in infringement suits brought against Barr and Natco in response to Paragraph IV Certifications they filed. (IUB Compl., ¶¶ 213, 214, 226, 229.) The litigation is not in dispute and the complaints sufficiently allege facts that support plaintiffs’ theory that Celgene mounted the lawsuits to enforce illegally obtained patents, satisfying the second prong of a *Walker Process* claim. Celgene’s motion to dismiss plaintiffs’ Sherman Act claim on *Noerr Pennington* immunity grounds is denied.

[10] The Court notes that Celgene neglected to provide the Distribution Patents’ applications or prosecution history, further buttressing the plausibility of plaintiffs’ allegations. *See Hydril*, 474 F.3d at 1349 (finding that, in the absence of the patent applications or prosecution history, that plaintiffs’ allegations were sufficient to plead a claim of *Walker Process* fraud).

ii. <u>Sham Litigation</u>

A plaintiff contending that a defendant engaged in sham litigation must plead facts that show the lawsuit was "(1) 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits' (the objective element), and (2) motivated by a desire 'to interfere *directly* with the business relationships of a competitor' (the subjective element)." *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, 762 F.3d 1338, 1343 (Fed. Cir. 2014) (quoting *PRE*, 508 U.S. at 60-61).

Litigation is objectively baseless if it is brought without probable cause. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1007 (Fed. Cir. 2012). But, "[n]either the bringing of an unsuccessful lawsuit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suit to antitrust liability," *C.R. Bard*, 157 F.3d at 1369, and "evidence of anticompetitive intent or purpose" alone will not transform an objectively reasonable lawsuit into a sham. *PRE*, 508 U.S. at 59. It must be shown "that plaintiff's case [had] no objective foundation, and the plaintiff must actually know this." *iLOR, LLC v. Google, Inc.*, 631 F.3d 1372, 1377 (Fed. Cir. 2011).

Plaintiffs argue that several of their allegations allow the Court to infer that Celgene's patent infringement suits were objectively baseless, which include those asserting Celgene obtained the Distribution Patents by fraud and that it entered into reverse payment agreements with Barr and Lannett because the settlements evince Celgene's knowledge that the Distribution Patents were unenforceable. Plaintiffs' factual allegations showing that Celgene procured the Distribution Patents by committing fraud plausibly show that the patent infringement suits were objectively baseless because a reasonable litigant would know that a lawsuit to enforce invalid patents is without probable cause. *See C.R. Bard*, 157 F.3d at 1368 ("Conduct prohibited under antitrust

laws includes bringing suit to enforce a patent with knowledge that the patent is invalid or not infringed, and the litigation is conducted for anticompetitive purposes."); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D. Del. 2006) (finding that plaintiffs sufficiently alleged that the defendant's patent infringement suits were objectively baseless because it knew that the patents were unenforceable).

Plaintiffs argue they pleaded other facts that plausibly support that Celgene engaged in sham litigation -- specifically that it entered into settlements with Barr and Lannett that were pay-for-delay agreements. They allege Celgene paid the two manufacturers either to delay or not to market their generic versions of thalidomide until a certain event or point in time. (IUB Compl., ¶¶ 213, 214, 217.) According to plaintiffs, Celgene also "may have agreed to sell Thalomid to Lannett under the terms of the settlement, because Lannett announced in late 2014 that its bioequivalence studies were going well, and it expected to submit an ANDA" in January 2014. (*Id.* ¶ 240.)

The Supreme Court recently addressed such pay-for-delay, or reverse payment agreements in *Actavis*, holding that under certain circumstances, such arrangements may violate the Sherman Act. *Actavis*, 133 S. Ct. 2237. Essentially, the Court found that for a reverse payment to raise possible antitrust implications and cast doubt on a patent's validity: (1) there must be a "reverse payment"; (2) that is "large and unjustified"; (3) that the payor is "unable to explain and to justify." *Id.*

The Court recognizes that plaintiffs do not allege facts going to the amount of any "reverse payment" to Barr and Lannett. What remains troubling is Celgene's insistence, in its reply to plaintiffs' arguments on this point, that because of its large portfolio of patents covering Thalomid and Revlimid, competitors could not enter the market. This pushes aside the fact that the

complaints here arise out of the particular nature of Hatch-Waxman. The plaintiffs allege that by various means that directly had an impact on the requirements for ANDAs, Celgene carefully blocked or delayed generic manufacturers' entry into the market over which it had monopoly power. At this stage of the litigation, the Court is reluctant to dismiss claims of sham litigation when plaintiffs' theory is clearly enunciated in the complaints and the facts in support connect the litigation to delay to the injury complained of.

The Court also finds that in context, the filing of the citizen petition may be seen as consistent with efforts to block entry into the thalidomide and lenalidomide markets. It is not determinative of the plausibility of the facts pled that the FDA did not take action on the citizen petition, as Celgene argues. Plaintiffs are asserting that Celgene's litigation is causally connected to its overall anti-competitive scheme whereby it first blocked its competitors' access to its drugs by refusing to providing samples for bioequivalency testing, and then sued the same competitors after they were able to obtain sufficient samples to conduct testing and file ANDAs.

b. The Non-Distribution Patents

Celgene's second standing argument rests on the "almost three-dozen" patents that it owns, which cover Thalomid and Revlimid and are not challenged here as invalid ("the Non-Distribution Patents"). Even if its enforcement of the Distribution Patents were anti-competitive, Celgene argues, it could prevent generic drug manufacturers from entering the thalidomide and lenalidomide markets by raising the Non-Distribution Patents in an infringement action. In its moving brief, Celgene asserts that the Non-Distribution Patents "explain[s] the absence of generic competition of Revlimid and Thalomid," and therefore, plaintiffs fail to allege antitrust injury and causation because their payment of supracompetitive prices is not solely attributable to its alleged anti-competitive conduct. (Celgene Br. at 16.)

As plaintiffs note in their opposition, this argument would essentially require them to discredit all possible intervening causes of an injury in their complaint to demonstrate standing. But the law does not demand that plaintiffs "allege all alternative theories of causation to survive a motion to dismiss. . . . Plaintiffs are simply required to allege facts showing that they suffered the type of injury or harm the antitrust laws were intended to prevent, and that their injury flows from [Celgene's] anti-competitive conduct." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004) (Greenaway, J.) (hereinafter "*K-Dur (2004)*"); *see also Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969) ("[A] plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable [antitrust] injury . . . ."). Therefore, at this stage of the litigation, whether Celgene owned other patents by which it could lawfully exclude generic competition from the thalidomide and lenalidomide markets is not the point.[11]

These complaints allege how Celgene manipulated the FDA regulatory scheme, particularly the Hatch-Waxman Act, to "block[] and delay[] generic Thalomid and Revlimid competition." (IUB Compl., ¶ 243.) Plaintiffs assert facts supporting their claims of anti-competitive conduct: that Celgene engaged in sham litigation, and that it used its restricted distribution programs as a pretext to withhold samples for bioequivalency testing in order to

[11] Celgene also argues that the Court may use Fed. R. Evid. 201(b) to take judicial notice of the Non-Distribution Patents and their validity based on their listings in the Orange Book. Fed. R. Evid. 201(b) permits a court to take judicial notice of an adjudicative fact "that is not subject to dispute because it is (1) generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." The Court may take judicial notice of the fact that Celgene's Non-Distribution Patents are listed in the Orange Book as a matter of public record, *see Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014), but cannot deem the listings as proof of their validity when the FDA admits that it does not review the patent information submitted as part of an NDA. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 792 F.3d 388, 395 (3d Cir. 2015); *see also aaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002) ("[The FDA] explain[s] that it lacks both the resources and the expertise to police the correctness of Orange Book listings."). Furthermore, patents "should not be irrebuttably presumed valid" because of "the public interest support[ing] judicial testing and elimination of weak patents." *King Drug*, 792 F.3d at 398 (alteration in original) (citation and internal quotation marks omitted).

prevent generic competitors from entering the thalidomide and lenalidomide markets (IUB Compl., ¶ 243, 246.), which is the type of conduct antitrust laws were aimed to prevent because it "impairs the opportunity of rivals" without "further[ing] competition on the merits." *Broadcom Corp.*, 501 F.3d at 308. And plaintiffs allege this conduct resulted in them paying supracompetitive prices for Thalomid and Revlimid due to the lack of generic competition in thalidomide and lenalidomide markets—a quintessential antitrust injury. *See Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 n.11 (9th Cir. 2012) (noting that reduced consumer choice and increased price constitute antitrust injury when caused by anti-competitive practices). The Court therefore finds that plaintiffs' factual allegations sufficiently plead antitrust injury and causation.

2. <u>Celgene's Refusal to Deal</u>

Celgene challenges the sufficiency of plaintiffs' allegations founded on its refusal to provide Thalomid and Revlimid samples to generic drug manufacturers for bioequivalency testing. It contends that, in order to state a Section 2 Sherman Act claim based on a refusal to deal, the plaintiff must show that the defendant terminated a prior course of dealing with a competitor and that it had no legitimate business justification for doing so. Implicit in plaintiffs' arguments is that a prior course of dealing is not a necessary element of a refusal-to-deal claim.

"As a general rule, businesses are free to choose the parties with whom they will deal . . . ." *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 448 (2009); *see also King Drug*, 791 F.3d at 409 n.32. Requiring a business to cooperate with competitors "is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, rival, or both" to innovate. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407-08 (2004). "Courts are ill suited 'to act as central planners, identifying the proper price,

quantity, and other terms of dealing.'" *Linkline*, 555 U.S. at 452 (quoting *Trinko*, 504 U.S. at 408). And of most concern is that forced cooperation and negotiation between competitors may facilitate "the supreme evil of antitrust: collusion." *Trinko*, 540 U.S. at 408.

"The high value . . . placed on the right to refuse to deal with other firms does not mean the right is unqualified," however. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985). A business may freely choose with whom to deal except where its motivation is to obtain or maintain a monopoly. *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). However, a Sherman Act violation for a refusal to deal "is near the outer boundary of § 2." *Trinko*, 540 U.S. at 409.

The parties dispute the validity of this claim based on competing interpretations of the Supreme Court's decision in *Aspen Skiing*, specifically whether, under that decision, the termination of a prior course of dealing between the defendant and a competitor is a necessary element of a Section 2 refusal-to-deal claim. In *Aspen Skiing*, the defendant, Ski Co., the owner of three of four ski areas in Aspen, Colorado, ceased cooperating with the owner of the fourth, Highlands, in selling a multi-mountain six-day pass for use at any of the four ski areas. Ski Co. replaced it with a six-day pass that was limited to its three ski mountains, and would only agree to reinstate the four-mountain pass if Highlands accepted a fixed percentage of the revenue, allocating Highlands far less than what it had been getting. Highlands responded by marketing its own four-mountain pass, but Ski Co. refused to sell Highlands passes to its three ski areas, even at retail value. Highlands' market share for downhill skiing in Aspen tumbled after Ski Co. unilaterally terminated the four-mountain ski pass program.

The Supreme Court found these facts sufficient to conclude that Ski Co.'s refusal to deal violated the Sherman Act as being motivated by anti-competitive goals. The Supreme Court noted

that the inquiry should be limited not just to the effect of Ski Co.'s conduct on its competitor, Highlands, but also on consumers, and "whether it has impaired competition in an unnecessarily restrictive way." *Aspen Skiing*, 472 U.S. at 605. It found that "[i]f a firm has been attempting to exclude rivals on some basis other than efficiency, it is fair to characterize its behavior as predatory." *Id.* The Court determined that the elimination of the four-area ticket adversely affected consumer choice as well as having a negative impact on Highlands' ability to compete. *Id.* at 606-08. Moreover, the Court reasoned that Ski Co.'s justifications for refusing to deal with Highlands were pretextual. *Id.* at 608-09. Ski Co. offered no efficiency justifications and an argument that it was too difficult to monitor skier mountain usage under the four-mountain pass was without merit because that had been done successfully in the past. *Id.* at 608-09. Ski Co. also claimed that Highlands' ski area's quality was inferior, and the Court dismissed that argument as pretextual because the four-area pass allowed the skiers to choose based on quality. *Id.* at 610.

The Court concluded that the evidence "support[ed] an inference that the monopolist made a deliberate effort to discourage its customers from doing business with its smaller rival" and that "Ski Co. was not motivated by efficiency concerns and . . . was willing to sacrifice short-run benefits and consumer goodwill in exchange for the perceived long-run impact on its smaller rival." *Id.* at 610-11. Thus, the Court looked at all the facts surrounding Ski Co.'s refusal to deal with Highlands as circumstantial evidence to support the inference that it acted with anti-competitive intent because, as the Court noted earlier in its opinion, "no monopolist monopolizes unconscious of what he is doing." *Id.* at 602 (citation and internal quotation marks omitted).

The reasoning behind *Aspen Skiing* was revisited by the Supreme Court in *Trinko* where the plaintiffs alleged that the defendant, Verizon, violated Section 2 of the Sherman Act by refusing to provide its competitors with access to its communication network, conduct for which the

government had penalized Verizon under the Telecommunications Act of 1996. The Court rejected the plaintiffs' claim, declining to extend *Aspen Skiing* to Verizon's conduct. *Trinko,* 540 U.S. at 409. The Court noted that in *Aspen Skiing* it found significant that Ski Co.'s "unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggested a willingness to forsake short-term profits to achieve an anti-competitive end, and also that the defendant's unwillingness to renew the ticket *even if compensated at retail price* revealed a distinctly anticompetitive bent." *Id*. Verizon's prior conduct, unlike Ski Co.'s, "shed[] no light upon the motivation of its refusal to deal upon whether it[] . . . [was] prompted not by competitive zeal but by *anticompetitive malice.*" *Id.* (emphasis added).

Celgene reads *Aspen Skiing* and *Trinko* too narrowly. The termination of the dealing between Ski Co. and Highlands was used as circumstantial evidence of Ski Co.'s demonstrated anti-competitive motivation, along with its lack of legitimate business justifications for doing so.

Both decisions indicate that motivation is central. The Court agrees with the plaintiffs that at this point it is too soon to measure motivation on Celgene's part. The facts asserted are that Celgene provided samples to researchers who were not seeking to enter the market, but not to competitors, who were. Plaintiffs specify that Mylan and Lannett gave Celgene letters from the FDA that stated that the agency would not take action should Celgene provide samples to them. Celgene continued to refuse to deal. This raises a plausible inference that Celgene's reliance on its distribution programs is pretextual.[12]

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[12] Both parties brought to the Court's attention a recent decision in which a court dismissed a plaintiff's refusal-to-deal claim when a drug manufacturer cited a restricted distribution program as the reason for its refusal to sell the plaintiff drug samples for bioequivalency testing. *Natco Pharma Ltd. v. Gilead Scis., Inc.*, 2015 WL 5718398, at *6 (D. Minn. Sept. 29, 2015). The primary difference between the present matter and that matter, however, is that the plaintiff never alleged that the FDA informed the defendant that its restricted distribution program could not be relied on in denying potential generic manufacturers access to samples.

Celgene offers the additional justification that "certain states . . . purport to hold branded manufacturers . . . liable for the injuries caused by generic copies of their drugs," relying on several cases where courts have held a brand name manufacturer liable for injuries caused by generic manufacturer's drug. (Celgene Br. at 35.) As plaintiffs argue in their opposition, Celgene overstates the basis on which liability is extended to a brand name manufacturer.

Those states holding brand name manufacturers liable do so on a failure-to-warn theory. *See, e.g.*, *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708-09 (D. Vt. 2010); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 318 (Cal. Ct. App. 2008). These decisions rely on the laws regulating a generic drug's labeling, which require it to use the identical labeling that was approved for the brand name drug. 21 U.S.C. § 355(j)(2)(A)(v). These courts held that a brand name manufacturer owes a duty to a consumer injured by a generic manufacturer's drug when a risk of that drug is not adequately disclosed on the its labeling because the generic drug must use the same labeling as the brand name drug. *Kellogg*, 762 F. Supp. 2d at 708-09. A brand name manufacturer would not be liable for defects in the generic drug's formulation or manufacture. *Conte*, 85 Cal. Rptr. 3d at 317 n. 16. In fact, a failure-to-warn claim relies on the fact that the brand name and generic drugs are bioequivalents, having the same formulation. *See id.* at 307. The possibility that Celgene could be liable for a generic drug's harm is therefore not a legitimate justification that would support its refusal to supply generic manufacturers with samples of Thalomid and Revlimid.

Plaintiffs' allegations plausibly show that Celgene lacked a legitimate business justification for withholding samples of its drugs.

3. **Celgene's Overall Anti-Competitive Scheme**

Celgene moves to dismiss plaintiffs' fourth count in its entirety by arguing that plaintiffs fail to state claim under Section 2 of the Sherman Act because each individual act that they allege to be part of its overall anti-competitive scheme is not itself an antitrust violation. This argument, however, takes too narrow a view of what a plaintiff must plead to state claim under Section 2.

A court must look at allegations about a defendant's anti-competitive conduct as a whole, *LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003), and its legal analysis must not "tightly compartmentaliz[e] the various factual components" of a plaintiff's allegations, "wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962); *see also Abbott Labs.*, 432 F. Supp. 2d at 428. A court assessing the anti-competitive effect of a defendant's overall scheme must consider "the increase in the defendant's market share, the effects of foreclosure on the market, benefits to customers and the defendant, and the extent to which customers felt they were precluded from dealing with other manufacturers." *LePage's*, 324 F.3d at 162.

Plaintiffs plausibly assert that Celgene procured the Distribution Patents by committing fraud on the USPTO and then sued potential generic competitors for infringement of those invalid patents such that its conduct is not protected by the *Noerr Pennington* Doctrine. Plaintiffs also adequately claim that Celgene manipulated the Hatch-Waxman Act by listing the Distribution Patents in the Orange Book and by filing infringement lawsuits to prevent or delay the approval of any ANDAs filed by generic competitors. As IUB characterizes the allegations in its opposition brief, Celgene "first block[ed] competitors' access to its drug for bioequivalence testing, and then su[ed] those same competitors when they managed to obtain the drug and file an ANDA." (D.E. 29 at 23.) These allegations allow the Court to infer that Celgene willfully sought to maintain its

monopoly in violation of Section 2 of the Sherman Act in order to charge supracompetitive prices, not through business acumen or a superior product, but through a concerted effort to deny potential generic competitors access to the market.

For the above reasons, Celgene's motion to dismiss count 4 of plaintiffs' complaints is denied.

C. State Law Claims – Count 1, Count 2, Count 3, and Count 5

Celgene requests the dismissal of plaintiffs' state law claims in their respective first, second, third, and fifth counts and raises four arguments that are equally applicable to both IUB's and Providence's complaints. Celgene first contends that plaintiffs lack Article III standing to assert claims on behalf of putative class members under the laws of states in which they have not alleged a personal injury. It also maintains that, pursuant to New Jersey choice-of-law rules, plaintiffs may only bring claims under the laws of Connecticut and Rhode Island and that all other state law claims must be dismissed. Celgene's third argument asserts that plaintiffs' state law claims are preempted by federal patent law because they rely on its alleged inequitable conduct before the USPTO. It focuses its final assertion on plaintiffs' unjust enrichment claims in their fifth counts, arguing that those claims rest on the same allegations as their state antitrust claims and that unjust enrichment claims cannot be used as an end-run around state antitrust laws. Celgene further contends the individualized nature of the harm inherent in unjust enrichment claims precludes class certification.

1. Article III Standing for State Law Claims

Celgene argues that plaintiffs lack Article III standing to assert claims on behalf of putative class members under the laws of states in which they either have not alleged an injury or do not reside. Constitutional standing, under Article III, requires a plaintiff to show: (1) it suffered an

injury-in-fact, that is "concrete and particularized" and "actual or imminent," and not merely "conjectural or hypothetical"; (2) that the defendant's complained of conduct caused that injury; and (3) that it is likely, "as opposed to merely speculative," a favorable decision by the court will redress the injury. *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007). "[N]amed plaintiffs who represent a class 'must allege and show that they have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.'" *Lewis v. Casey*, 518 U.S 343, 357 (1996) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n.20 (1976)). "Once threshold individual standing by the class representative is met, a proper party to raise a particular issue is before the court, and there remains no further separate class standing requirement in the constitutional sense." *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 306-07 (3d Cir. 1998) (citation and internal quotation marks omitted) (hereinafter "*In re Prudential*"). Celgene contends IUB has standing in only three states, Connecticut, Massachusetts, and Nebraska, and that Providence has standing in five, Rhode Island, Kansas, Massachusetts, New Jersey, North Carolina, and Pennsylvania.

Plaintiffs respond that Celgene conflates Article III standing with class certification issues under Fed. R. Civ. P. 23, and that for Article III standing purposes it is sufficient to show they have suffered a personal injury. They note Celgene concedes they satisfactorily alleged injury in certain states, and argue that whether they can raise claims on behalf of absent class members under the laws of states where they did not suffer an injury is a question appropriate for the class certification stage, which must follow the resolution of any Article III standing questions.

The Third Circuit recently addressed the last point in *Neale v. Volvo Cars of North America*, 794 F.3d 353, 360 (2015), finding that "considerations under Rule 23 are themselves

procedural rules, and thus rarely can be antecedent to the question of whether a federal court has jurisdiction to hear a claim at all," and so an Article III standing inquiry is a necessary prerequisite to Fed. R. Civ. P. 23 considerations. The court reasoned that delaying the standing analysis until after class certification could result in an advisory opinion—an act of "ultra vires." *Id.* at 361 (internal quotation marks omitted) (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998)).

IUB, which is located in Connecticut, alleges to have paid and/or reimbursed its members for the price of Thalomid and Revlimid in Massachusetts and Nebraska. (IUB Compl., ¶ 12.) Providence is based in Rhode Island, and it claims it paid or reimbursed its members for the price of the two brand name drugs in Florida, Kansas, Massachusetts, New Jersey, North Carolina, and Pennsylvania. (Providence Compl., ¶ 14.) Celgene, for purposes of its motions to dismiss, accepts that plaintiffs allege injuries in those states. The Court finds that the factual allegations discussed above support plaintiffs' standing to pursue state law claims because they show that Celgene's anti-competitive conduct caused their claimed injury in paying supracompetitive prices by unlawfully excluding generic competition. Further, plaintiffs seek damages for their state law claims, so a favorable decision will redress their injury. Plaintiffs therefore possess Article III standing to pursue their state law claims in those particular states.

The fact that plaintiffs have Article III standing, however, does not resolve the question of whether they can pursue state law claims on behalf of putative class members under the laws of states where they do not allege they suffered a personal injury. Celgene and plaintiffs point to cases that arrived at differing conclusions regarding this issue, but this authority offers little by way of legal analysis for their conclusions; the courts are either dismissing those state law claims or finding it premature to decide the issue. The Supreme Court, recently provided guidance in

Lexmark International, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1386 (2014) (citation and internal quotation marks omitted), where it stated that the limitation of a court's "power to resolve Cases or Controversies" flows from Article III, which sets out, along with the separation-of-powers principle, the "irreducible constitutional minimum of standing." Once the three-part test of (1) injury, (2) causation, and (3) redressability is satisfied, the Court emphasized that "a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging." *Id.* (citation and internal quotation marks omitted). The Court differentiated the zone-of-interests test, which it found was unrelated to standing and strictly a matter of statutory construction. *Id.* at 1387. That test "requires [a court] to determine, using traditional tools of statutory interpretation, whether a legislatively conferred cause of action encompasses a particular plaintiff's claim." *Id.* Unlike the question of Article III standing, the zone-of-interest test does not concern a court's subject matter jurisdiction—its "power" to hear the case, but whether the plaintiff states a claim—a merits question. *See id.* at 1387 n.3, 1387 n.4; *see also Chabad Lubavitch of Litchfield Cnty., Inc. v. Litchfield Historic Dist. Comm'n*, 768 F.3d 183, 201 (2d Cir. 2014) (elaborating that the zone-of-interests test does not involve a court's jurisdiction to hear a case or controversy under Article III).

Celgene's attack on plaintiffs' standing to pursue state law claims on behalf of absent class members is not an Article III jurisdictional issue under *Lexmark*. Celgene argues that plaintiffs must allege an in-state injury, but Article III's injury-in-fact requirement "has nothing to do with the text of the statute relied upon." *Steel Co.*, 523 U.S. at 97 n.2; *see also Lexmark*, 134 S. Ct. at 1386. Celgene's attempt "[t]o inject the condition that [p]laintiffs must satisfy certain elements of the state antitrust claims into a constitutional standing analysis . . . result[s] in an impermissible out-of-the-box merits inquiry." *Processed Egg*, 851 F. Supp. 2d 867, 886 (E.D. Pa. 2012); *see*

also Nesbit v. Gears Unlimited, Inc., 347 F.3d 72, 80 (3d Cir. 2003) ("The [Supreme] Court also criticized the implications of treating the validity of a cause of action as jurisdictional.").

In this opinion the Court has determined that there is a live case or controversy sufficient to invoke its subject matter jurisdiction under Article III. Plaintiffs correctly conclude that whether they may pursue these claims is better left for the class certification stage because "the issue now [becomes] one of compliance with the provisions of Rule 23, not one of Article III standing." *In re Prudential*, 148 F.3d at 307 (alteration in original) (citation and internal quotation marks omitted); *see also Sosna v. Iowa*, 419 U.S. 393, 403 (1975) (noting that, once Article III standing is established, the focus shifts to whether the plaintiff will adequately represent the interests of the proposed class under Fed. R. Civ. P. 23(a)). Celgene's motion to dismiss all of plaintiffs' claims under the laws of states in which they do not allege a personal injury in their first, second, third, and fifth counts is denied.

2. Choice of Law

Celgene also argues that all of plaintiffs' state law claims in in their first, second, third, and fifth counts must be dismissed because New Jersey choice of law rules require the Court to apply Connecticut law to all of IUB's claims, which Celgene contends bars indirect purchasers, like IUB, from pursuing antitrust damages claims and prohibits IUB from raising unfair competition or unjust enrichment claims on the same facts as a way to plead around this prohibition. It makes a similar argument regarding Providence's claims. Plaintiffs contend that it is premature at the motion-to-dismiss stage to engage in a choice-of-law analysis before class certification.

A court's determination about "whether a choice-of-law issue is ripe or premature should be made on a case-by-case basis depending on the facts presented." *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 445 (D.N.J. 2012) (Wolfson, J.) While a court may resolve a choice-of-law

question on a motion to dismiss, *see Cooper v. Samsung Elecs. Am., Inc.*, 374 F. App'x 250, 255 (3d Cir. 2010), it should defer engaging in such an analysis if the facts are, as of yet, under developed to decide the issue. *See K-Dur 2004,* 338 F. Supp. 2d at 541 (declining to decide which state laws would apply because the class of plaintiffs had yet to be certified); *see also In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 534 (E.D. Pa. 2010) ("[C]hoice-of-law issues may be determined at or after class certification."). A court should exercise caution prior to class certification when asked to resolve choice-of-law questions "in a nationwide class action where an array of factors beyond the residence of the class members must be considered, including . . . the location of the parties and the purchased items." *Sullivan v. DB Investments, Inc.*, 667 F.3d 273, 309 (3d Cir. 2011).

Celgene's argument that the Court should conduct a choice-of-law analysis is undermined by the fact that many of the cases it relies on were decisions made on motions for summary judgment. *See In re K-Dur Antitrust Litig.*, No. 01-1652, 2008 WL 2660783, at *1-2 (D.N.J. Mar. 19, 2008) (Orlofsky, Special Master) (hereinafter "*K-Dur (2008)*"); *In re Rezulin Prods. Liability Litig.*, 392 F. Supp. 2d 597, 606 (S.D.N.Y. 2005); *Am. Rockwool, Inc. v. Owens-Corning Fiberglas Corp.*, 640 F. Supp. 1411, 1418 (E.D.N.C. 1986). In fact, the court in *K-Dur (2008)* had previously refused to undertake a choice-of-law analysis, finding it to be premature on a motion to dismiss. *See K-Dur (2004)*, 338 F. Supp. 2d at 541.

Based on the above, the Court will defer its decision regarding the validity of any claims under particular state laws until the facts are further developed about the residence of putative class members or the state where they purchased or reimbursed their members for the price of Thalomid and Revlimid, and where the absent class members suffered an injury. The Court also does not address Celgene's motions to dismiss specific claims in plaintiffs' first, second, third, and fifth

counts because it "is unwilling to predict which state law(s) would be applicable in the event the class is certified." *K-Dur (2004)*, 338 F. Supp. 2d at 541.

For the foregoing reasons, Celgene's motion to dismiss individual state law claims in the complaints is denied.

3. <u>Federal Preemption</u>

Celgene's also contends that all of plaintiffs' state law claims are preempted by federal patent law because they primarily rely on the allegations that it obtained the Distribution Patents through inequitable conduct on the USPTO. Plaintiffs maintain that their state law claims are not preempted by federal patent law because they rely on more than Celgene's alleged misconduct before the USPTO and also contain the element of bad faith misconduct in the market place.

"Federal Circuit law governs whether federal patent law preempts a state law claim," *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed. Cir. 2005), and it preempts any state law causes of action that are based on nothing more than misconduct before the USPTO. *See Semiconductor Energy Lab., Ltd. v. Samsung Elecs. Co., Ltd.*, 204 F.3d 1368, 1382 (Fed. Cir. 2008). But a state law claim is not preempted "even if it requires the state court to adjudicate a question of federal patent law," so long as it contains additional elements not part of a federal patent cause of action. *Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470, 1473 (Fed. Cir. 1998). These additional elements, as plaintiffs note, often include allegations regarding bad faith conduct in the marketplace committed by the patentee. *See Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed. Cir. 1999) (finding that a state-law tortious interference claim was not preempted by federal patent law because the plaintiff must show the defendant acted in bad faith). For example, in *Dow* the court found that the plaintiffs' interference with contractual relations cause of action was not preempted by federal patent law because, although the tort claim relied, in part,

on inequitable conduct before the USPTO, "but rather was premised upon bad faith misconduct in the marketplace." *Dow*, 139 F.3d at 1477

Plaintiffs' claims, while alleging that Celgene committed fraud before the USPTO, are also premised on bad faith misconduct in the thalidomide and lenalidomide markets. They assert that Celgene obtained the Distribution Patents through fraud, enforced those patents knowing they were invalid, and manipulated the FDA regulations, all to foreclose generic competition so it could continue to charge supracompetitive prices for Thalomid and Revlimid. These allegations go beyond just claiming fraud on the USPTO and, rather, focus on Celgene's acts in the marketplace and form the foundation of all of plaintiffs' state law claims. The Court therefore agrees with plaintiffs that their state law claims are not preempted by federal patent law because they go beyond Celgene's alleged misconduct before the USPTO by claiming Celgene's acts also involved marketplace misconduct and denies Celgene's motion to dismiss plaintiffs' state law claims as preempted.

4. <u>Count 5 - Unjust Enrichment</u>

Celgene contends that plaintiffs' unjust enrichment claims rely entirely on their allegations that Celgene violated antitrust laws and that a plaintiff cannot bring a corresponding unjust enrichment claim as a means to avoid a state's antitrust law's bar against damages claims by indirect purchasers. Celgene also maintains that the type of harm alleged when bringing an unjust enrichment claim is too individualized to permit class certification. Plaintiffs' primary opposition is that it is premature to decide these issues prior to class certification.

Plaintiffs may plead alternative theories of recovery in their complaints, and it is too soon now, prior to discovery, to make the determination that plaintiffs' unjust enrichment claims are brought to evade a state's rule about the litigation rights of indirect purchasers. *See In re*

Hypodermic Prods. Antitrust Litig., No. 05-1602, 2007 WL 1599225, at *16 (D.N.J. 2007) (Linares, J.) (declining to dismiss unjust enrichment claims when the defendant argued they were redundant of plaintiffs' antitrust claims because it was premature to do so). And whether the individualized nature of the harm will preclude class certification is a question of predominance better left for class certification for when a more developed factual and legal record is before the Court so that it may conduct the "rigorous analysis" Fed. R. Civ. P. 23 requires. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 309 (3d Cir. 2008). The Court therefore denies Celgene's motion to dismiss unjust enrichment claims.

IV. Conclusion

For the foregoing reasons, Celgene's motion to dismiss all counts in plaintiffs' complaints is denied. An appropriate order will be entered.

/s/ Katharine S. Hayden

Dated: October 29, 2015 — Katharine S. Hayden, U.S.D.J.